K092682

DEC 11 2009

510(k) Summary of Safety and Effectiveness
Gyrus ACMI Inc.
Gyrus ACMI Flexible Endoscope Storage-Sterilization Trays

General Information

Manufacturer:	Gyrus ACMI Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Contact Person:	Lorraine Calzetta Regulatory Affairs Tel. #: 508-804-2752 Fax #: 508-804-2624
Date Prepared:	December 3, 2009

Device Description

	Classification Name: Sterilization, wrap, containers and trays (21CFR 880.6850), Class II or Accessories to Endoscope (21CFR876.1500) Class II
Trade Name:	Gyrus ACMI Flexible Endoscope Storage-Sterilization Trays
Generic/Common Name:	Endoscope and accessories

Predicate Devices

Symmetry Medical PolyVac Instrument Delivery System	K040223
Olympus Sterilization Trays	K033222

Intended Uses

The Gyrus ACMI® Flexible Endoscope Storage-Sterilization Trays are intended to be used to enclose and protect Gyrus ACMI flexible endoscopes during sterilization. The trays are to be used in conjunction with an FDA cleared sterilization wrap. The trays are optional accessories to the Gyrus ACMI endoscopes for which they are designed. Maintenance of sterility depends on the sterilization wrap, not the tray.

The trays are indicated for ETO sterilization of **only** of the following :

Gyrus ACMI Flexible Endoscopes

ICN	ICN-0564, ICN-0565
DUR-D	DUR-D, DUR-DBA

ACN	ACN-2T, ACN-2TBA
DUR-8	DUR-8, DUR-8-BA, DUR-8E, DUR-8E-BA,DUR–8 Ultra
AUR	AUR-7, AUR-735

EtO Sterilization parameters:
EtO Sterilize using 100% ethylene oxide
Temp: 55 °C, Vacuum 97mmHgV, Preconditioning time 60 minutes, EtO concentration 725-750 mg/L, Exposure time 60 minutes, Humidity 35%-80%, Aeration: 12 hours @55 °C

Product Description

The Gyrus ACMI® Flexible Endoscope Storage-Sterilization trays are comprised of plastic lids and bottoms that contain numerous large holes (approximately 7mm in diameter) that permit ready ingress and egress of sterilization gases. The trays are designed to provide protection from physical damage to the flexible endoscope during sterilization and storage. The trays are constructed of biocompatible RADEL-R. The trays do not contact the patient. Radel-R is a polyphenylsulfone plastic that is widely used in medical devices. Radel-R meets the requirements for biocompatibility pursuant to ISO-10993 and is compatible with EtO sterilization.

Performance Data

The PCDs (process challenge devices) were placed in the trays and inoculated with FDA cleared biological indicator organisms, and chemical indicators were placed. The trays were wrapped with two layers of FDA approved sterilization wrap and placed into ethylene oxide sterilizer for processing. The system was sterilized successfully in a 30 minute half cycle demonstrating 6 log reduction capability (SAL of 10-6). Test systems were exposed to 60 minute full cycles and ethylene oxide residual testing was performed, with a 12 hour aeration time. Pursuant to ISO10993-7, residual concentrations were within acceptable limits.

Technological Characteristics and Substantial Equivalence

The Gyrus ACMI® Endoscope Storage-Sterilization Trays are composed of the same materials and utilize similar features as that of the predicates.

In summary, the Gyrus ACMI Endoscope Storage Sterilization Trays are substantially equivalent to the predicate device and presents no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 11 2009

Ms. Lorraine Calzetta
Regulatory Affairs
Gyrus ACMI, Incorporated
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K092682
Trade/Device Name: Gyrus ACMI® Flexible Endoscope Storage-Sterilization Trays
Regulation Number: 21CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: October 21, 2009
Received: November 6, 2009

Dear Ms. Calzetta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

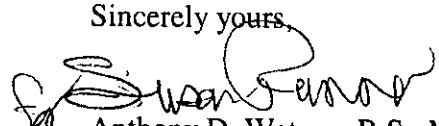
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Gyrus ACMI® Flexible Endoscope Storage-Sterilization Trays

510(k) Number: K092682

Device Name: Gyrus ACMI® Flexible Endoscope Storage-Sterilization Trays

Indications for use:

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Prescription Use: ____ **OR** Over-the-Counter Use: ___X___
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth P. Claverie-Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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